UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

AAT BIOQUEST, INC.,

Plaintiff,

v.

TEXAS FLUORESCENCE LABORATORIES, INC.,

Defendant.

Case No. 14-cv-03909-DMR

ORDER GRANTING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Dkt. No. 27, 35

Before the court are cross-motions for summary judgment pursuant to Federal Rule of Civil Procedure 56 filed by Plaintiff AAT Bioquest Inc. ("AAT") and Defendant Texas Fluorescence Laboratories ("TEFLabs").[1] The court conducted a hearing on March 3, 2015. After full consideration of the parties' submissions and oral argument, for the reasons stated below, the PMSJ is granted, and the DMSJ is denied.

I. FACTS

A. The Complaint

AAT brings this complaint against TEFLabs for infringement of AAT's United States Patent No. 8,779,165 ("the '165 Patent"), entitled "Fluorescent Ion Indicators[2] and Their Applications." Compl. [Docket No. 1] at ¶¶ 12-18. AAT sells a fluorescent calcium ion indicator called Fluo-8 AM, which is an embodiment of Claim 1 of the '165 Patent.

[1] The parties' cross-motions were sequentially briefed: TEFLabs filed its motion first [Docket No. 27, "DMSJ"], then AAT filed its response and cross-motion [Docket No. 35, "PMSJ"]. TEFLabs next filed a reply [Docket No. 36, "Reply"], followed by AAT's surreply [Docket No. 39, "Surreply"].

[2] Fluorescent ion indicators are also referred to as "fluo calcium ion indicators" or "fluo indicators."

TEFLabs concedes that it makes and sells a fluorescent calcium ion indicator with the same structure as Fluo-8 AM, which it calls "Fluo-2 MA AM." TEFLabs also admits that Fluo-2 MA AM infringes Claim 1 of the '165 Patent. Answer [Docket No. 11] at ¶ 7. However, it asserts various defenses based on the invalidity of the patent and AAT's alleged inequitable conduct. The viability of these defenses is the sole issue in the parties' motions.

B. Overview of Technology

The basic facts regarding the technology at issue are not disputed. The '165 Patent involves calcium ion indicators, which are chemical compounds that detect the presence and quantity of calcium ion in a cell. Calcium ion indicators are also referred to generically as "dyes," because they attach to and highlight the target calcium ion. Calcium ion indicators typically contain (1) a binding component[3] that attaches (or "chelates") to calcium ion and (2) a reporter component that illuminates when the binding component binds to calcium ion, making it easier to observe the presence of calcium ion. They may also include Acetoxymethyl (AM) ester groups that assist the indicator in entering the cell, a process called "cell loading." For Fluo calcium ion indicators, the reporter component is based upon fluorescein, a fluorescent molecule. Calcium ion indicators based on rhodamine reporters are called rhod calcium ion indicators.

Fluo indicators are used to detect calcium ion through a procedure called an "intracellular calcium assay." The following chemical processes occur during an assay: the fluo indicator is added to living cells and internalized, or "loaded," into the cells. Once inside the cells, the indicator dye is hydrolyzed (i.e., the AM ester is cleaved off the indicator), which activates the indicator to be capable of binding to calcium ion. The cells are then exposed to a substance that causes the release of calcium ions from within storage sites inside the cell. Once the calcium ions are released, they bind to the indicator. During this binding event, the properties of the indicator are changed and it becomes fluorescent. A light source is used to illuminate the calcium ions; the source most commonly used in the process relevant to this case is an argon laser emitting 488 nanometer wavelength light. A person can then measure the intensity of the fluorescence emitted from the cells, which indicates the amount of calcium ion in the cells.

[3] The binding component in the indicators at issue is called the "BAPTA ion chelator."

An indicator is more desirable if it loads quickly into a cell, followed by rapid cleaving of the AM esters, because slow cleavage can cause the indicator to leak out of the cell. Another desirable characteristic is a strong fluorescence signal; a weak or "quenched" signal may make it more difficult to detect calcium ion. An indicator that can be loaded at a variety of temperatures is more desirable than an indicator that may only be loaded at a specific temperature. Another characteristic of an indicator is the "binding affinity" between the binding component of the indicator and the targeted calcium ion.[4] High-affinity binding results from greater molecular force between the targeted molecule and the binding component, while low-affinity binding involves less intermolecular force between the two.

C. Relevant Prior Art and Patent History

1. Prior Art: Tsien Patent

In 1991, a patent in the field of fluorescent calcium ion indicators was awarded to Roger Tsien and Akwasi Minta (United States Patent No. 5,049,673, or the "Tsien Patent"). Dr. Minta later founded TEFLabs in 1992.

2. Patent-in-Suit: '165 Patent

AAT was founded in 2006 by Dr. Zhenjun Diwu. On April 13, 2007, Dr. Diwu and several co-inventors filed United States Provisional Patent Application No. 60/923,452 ("the '452 Application" or the "provisional patent application"). The '452 Application was "directed to a family of fluorescent dyes that are useful for preparing fluorescent metal ion indicators."

On February 29, 2008, Dr. Diwu filed United States Patent Application No. 12/040,753 ("the '753 Application"), the non-provisional continuation of the '452 Application.

On March 11, 2011, Dr. Diwu filed a related patent application as United States Patent Application No. 12/932,683 ("the '683 Application"), which was a continuation of the then-pending '753 Application.[5] The Applicants disclosed the Tsien Patent as prior art in an Information Disclosure Statement dated June 20, 2011, during prosecution of the '683 Application. Claim 33 of the '683 Application, added by amendment on August 28, 2013,

[4] The targeted molecule is known generically as a "ligand."

[5] The '753 Application was eventually deemed abandoned on December 15, 2011.

discloses the subject matter of what eventually became Claim 1 of the '165 Patent.

The '683 Application was granted and issued as the '165 Patent on July 15, 2014.

II. LEGAL STANDARD

A. General Summary Judgment Standard

A court shall grant summary judgment "if . . . there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The burden of establishing the absence of a genuine issue of material fact lies with the moving party. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986), and the court must view the evidence in the light most favorable to the non-movant. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) (citation omitted). A genuine factual issue exists if, taking into account the burdens of production and proof that would be required at trial, sufficient evidence favors the non-movant such that a reasonable jury could return a verdict in that party's favor. *Id.* at 248. The court may not weigh the evidence, assess the credibility of witnesses, or resolve issues of fact. *See id.* at 249; *SCA Hygiene Products Aktiebolag v. First Quality Baby Products*, LLC, 767 F.3d 1339, 1347 (Fed. Cir. 2014) *vacated on other grounds*, 2014 WL 7460970 (Fed. Cir. Dec. 30, 2014) ("the district court [is] not permitted to assess the credibility of . . . witnesses on summary judgment").

To defeat summary judgment once the moving party has met its burden, the nonmoving party may not simply rely on the pleadings, but must produce significant probative evidence, by affidavit or as otherwise provided by Federal Rule of Civil Procedure 56, supporting the claim that a genuine issue of material fact exists. *TW Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987); *SCA Hygiene*, 767 F.3d at 1347 (party "may not rely solely on pleadings and speculation to create a genuine issue of material fact; it must identify particular evidence that creates such a dispute"). In other words, there must exist more than "a scintilla of evidence" to support the non-moving party's claims; conclusory assertions will not suffice. *Anderson*, 477 U.S. at 252. Similarly, "[w]hen opposing parties tell two different stories, one of which is blatantly contradicted by the record, so that no reasonable jury could believe it, a court should not adopt that version of the facts" when ruling on the motion. *Scott v. Harris*, 550 U.S. 372, 380 (2007).

Where, as here, the parties have filed cross-motions for summary judgment, "[e]ach motion must be considered on its own merits . . . . . In fulfilling its duty to review each cross-motion separately, the court must review the evidence submitted in support of each cross-motion." *Fair Hous. Council of Riverside Cnty., Inc. v. Riverside Two*, 249 F.3d 1132, 1136 (9th Cir. 2001). *See also Conceptus, Inc. v. Hologic, Inc.*, 771 F. Supp. 2d 1164, 1174 (N.D. Cal. 2010) (court considering simultaneous cross-motions for summary judgment in patent infringement action must consider evidentiary material identified and submitted in support of both motions before ruling on each of them) (citing *Fair Hous. Council*, 249 F.3d at 1134).

B. Standard for Summary Judgment of Invalidity

A patent is presumed valid. 35 U.S.C. § 282. This presumption can be rebutted, but the party challenging validity must meet the "high burden" of proving invalidity by "clear and convincing evidence." *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012). *See also U.S. v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988) ("The burden of proving invalidity . . . rests with the challenger . . . . [and] must be proven by facts supported by clear and convincing evidence."). The burden is especially high when the party challenging validity relies on the same evidence that was before the patent examiner. *Tokai Corp. v. Easton Enterprises, Inc.*, 632 F.3d 1358, 1367 (Fed. Cir. 2011) ("When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job.") (citations omitted).

"[A] moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise." *Eli Lilly v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001) (citing *Anderson*, 477 U.S. at 248). "Alternatively, a moving party seeking to have a patent held not invalid must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent." *Id.*

III. DISCUSSION

TEFLabs concedes its infringement of the '165 Patent and moves for summary judgment on the basis of four defenses:

(A) the '165 Patent is invalid because it fails to meet the written description requirement;

(B) the '165 Patent is invalid because it fails to meet the enablement requirement;

(C) the '165 Patent is invalid because it is obvious or anticipated; and

(D) the '165 Patent is unenforceable because of AAT's inequitable conduct.

The court analyzes each defense below.

A. Written Description Requirement

TEFLabs asserts the '165 Patent is invalid because it fails to meet the written description requirement under 35 U.S.C. § 112 ¶ 1.[6]

1. AAT's Motion to Strike

As a preliminary matter, AAT moves to strike the portions of the DMSJ related to the written description defense because TEFLabs did not assert it in either its Answer or its Invalidity Contentions, and instead raises it for the first time here.

"This district has adopted Patent Local Rules that 'require parties to state early in the litigation and with specificity their contentions with respect to infringement and invalidity.'" *Monolithic Power Sys., Inc. v. O2 Micro Int'l Ltd.*, No. C08-04567-CW, 2009 WL 3353306, at *2 (N.D. Cal. Oct. 16, 2009) (quoting *O2 Micro Int'l, Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1359 (Fed. Cir. 2006)). Patent L.R. 3-3(d) requires that a party provide "[a]ny grounds of invalidity based on . . . enablement or written description under 35 U.S.C. § 112(1)." "The rules are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *Mediatek Inc. v. Freescale Semiconductor, Inc.*, No. 11-cv-5341 YGR, 2014 WL 690161, at *1 (N.D. Cal. Feb. 21, 2014). "Any invalidity theories not disclosed pursuant to Local Rule 3-3 are barred, accordingly, from presentation at trial (whether through expert opinion testimony or otherwise)." *Id.*

[6] The Leahy-Smith America Invents Act, enacted in 2011, amended several parts of the Patent Act. The successor statute to 35 U.S.C. § 112 ¶ 1, which applies to patents filed after September 16, 2012, is codified at 35 U.S.C. § 112(a). Because the patent at issue was filed before September 16, 2012, the older version of the statutes apply.

Neither party supplied TEFLabs's Invalidity Contentions, but AAT submitted TEFLabs's response to an interrogatory asking TEFLabs to "identify all legal and factual grounds on which you contend that [the Asserted Claim] is unenforceable." *See* Carter Decl. at H. TEFLabs's response does not include a written description defense. Instead, the response identifies invalidity defenses based on anticipation, obviousness, enablement, and best mode. *Id.* at 14-18. TEFLabs now contends that the "best mode argument" that it disclosed in the interrogatory response was actually a written description argument. *See* Reply at 4 (TEFLabs "corrected" its invalidity argument "from best mode, which is a statutory requirement without teeth since 2013, to written description, which is still a basis for invalidity").

The disclosure of a "best mode" invalidity theory does not equate to the disclosure of a "written description" theory. S*ee Univ. Of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 921-22 (Fed. Cir. 2004) ("Although there is often significant overlap between the three requirements [written description, best mode, and enablement], they are nonetheless independent of each other."). However, upon review, TEFLabs's description of its best mode argument in its interrogatory response arguably suggests enough of a written description argument[7] that the court declines to strike that theory on the technical grounds that it was not previously disclosed.

2. Merits of Written Description Invalidity Defense

The written description requirement is set forth in the first paragraph of 35 U.S.C. § 112. In pertinent part, Section 112 ¶ 1 provides that:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112 ¶ 1. *See also Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1344 (Fed. Cir. 2013) *cert. denied*, 134 S. Ct. 1501 (2014).

To satisfy the written description requirement, "the description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad Pharm.*,

[7] *See, e.g.*, Carter Decl. at H at 18 ("The claimed compound was not *described* in any of the 34 examples") (emphasis added).

Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010). In other words, "the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Id.* Because the specification is viewed from the perspective of one of skill in the art, a patentee may rely on information that is "well-known in the art" for purposes of meeting the written description requirement. *See Falko–Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366-68 (Fed. Cir. 2006). "The written description inquiry presents an issue of fact." *Novozymes*, 723 F.3d at 1344 (citations omitted). *See also Union Oil Co. of California v. Atl. Richfield Co.*, 208 F.3d 989, 1001 (Fed. Cir. 2000) ("[W]ritten description questions are intensely factual, and should be dealt with on a case-by-case basis, without the application of wooden rules.").

TEFLabs failed to present any evidence relevant to this legal standard. TEFLabs did not address or provide evidence relating to: (1) the level of a person of ordinary skill in the art[8]; (2) the nature of the invention claimed; (3) what a person of ordinary skill in the art would have understood based on the disclosure within the four corners of the '165 Patent specification; or (4) what that person would have understood based on what was well-known in the art. TEFLabs presented only attorney argument to suggest that a person of ordinary skill in the art would not have understood the claimed invention to be adequately described.

Indeed, TEFLabs's briefs rely mostly on attorney argument, as they include virtually no citations to legal authority, and only minimal citations to mostly undifferentiated masses of evidence.[9] It is not the court's task to pan through these exhibits in an effort to discover

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[8] "Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field. These factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art." *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007).

[9] TEFLabs attached over 1,300 pages of exhibits to its opening brief and 65 pages of exhibits to its reply. The following sentence from the opening brief is typical of TEFLabs's tendency to cite to a mass of evidence in support of its attorney's conclusory argument: "In the '683 Application, AAT Bioquest submitted deceptive affidavits. 12932683_FILE_HISTORY." DMSJ at 45. The file history for the '683 Application is 427 pages long.

TEFLabs's argument. *See Digital Reg of Texas, LLC v. Adobe Sys., Inc.*, No. C 12-1971 CW, 2014 WL 3883437, at *1 (N.D. Cal. Aug. 6, 2014) (denying defendant's motion for reconsideration of judge's summary judgment order for plaintiff; "Adobe must explain its summary judgment arguments and cannot rely on the Court to sift through the countless exhibits to manufacture a summary judgment argument."); *Lockformer Co. v. PPG Indus., Inc.*, No. 99-C-6799, 2003 WL 1563703, at *2 n. 1 (N.D. Ill. Mar. 25, 2003) *aff'd*, 138 Fed. Appx. 314 (Fed. Cir. 2005) ("It is not the Court's task to search through the record to find evidence that supports PPG's position. Accordingly, the Court will not consider PPG's unsupported assertions and anticipated testimony in ruling on this motion [for summary judgment]").

TEFLabs's failure to provide any evidence or argument regarding what constitutes "persons of ordinary skill in the art" dooms its motion for summary judgment on the written description requirement. *See Suffolk Technologies, LLC v. AOL Inc.*, 752 F.3d 1358, 1367 (Fed. Cir. 2014) (granting summary judgment, and holding that "[w]ithout expert testimony" or other "affirmative evidence," "mere attorney argument" was insufficient to undermine credible testimony from defendant's expert). Without this evidence, the court cannot assess the most basic elements of the written description requirement, i.e., whether the description "clearly allow[s] persons of ordinary skill in the art to recognize that the inventor invented what is claimed."

In contrast, AAT's request for a judgment of "no invalidity" on the basis of written description includes competent expert testimony. AAT's expert Dr. Wayne Patton defines a person of ordinary skill in the art of fluorescent ion indicators as "a senior graduate student, postdoctoral fellow or practicing Master's degree or Ph.D. level scientist trained in organic chemistry who is familiar with the synthesis, properties and biological application of ion indicator dyes and might be engaged in practical research at a university, research institute, government laboratory or in industry." *See* Patton Decl. at ¶ 25. The basis for this definition is the doctorate-level education of '165 Patent inventor Dr. Diwu; the types of problems and prior art solutions encountered in the art; the relatively slow pace of innovation in the field; and the difficulty of identifying new chemical structures with improved qualities out of billions of possibilities. *Id.* at ¶ 26. Dr. Patton points to specific support in the relevant patent applications and concludes that

"[b]ased on [his] review, a person of ordinary skill in the art at the time of the invention would have understood the claimed compound to be adequately supported in both the provisional and utility applications." Patton Surreply Decl. [Docket No. 39-1] at ¶ 9. Based on this evidence, AAT concludes that a person of ordinary skill in the relevant art would have understood that the '165 Patent claimed Fluo-8 AM.

In response, rather than address Dr. Patton's testimony, TEFLabs offers two reasons why this court should ignore the "person of ordinary skill in the art" standard.[10] First, TEFLabs contends that "the test for written description is whether the structure for the compound of claim 1 was presented in the specification." *See* Reply at 3. According to TEFLabs, any lay person can determine that the written description requirement is not met here, because the structure for the compound is not present in the specification. This is not the law. The standard is not whether a specific chemical structure is set forth in the patent specification, but whether a person of ordinary skill in the art could read the patent specification and recognize that the inventor claimed what was invented. *See Union Oil*, 208 F.3d at 1001 ("The written description requirement does not require identical descriptions of claimed compounds, but it requires enough disclosure in the patent to show one of skill in this art that the inventor 'invented what is claimed.'"; finding substantial evidence of adequate written description in a patent for gasoline products in which the claims "do not describe each gasoline product in terms of molecular structures or lists of ingredients" but instead "specify the chemical properties of the gasolines"); *Ex Parte Sorenson*, 3 U.S.P.Q.2d 1462 (B.P.A.I. May 28, 1987) (an "appellant's specification need not describe the claimed invention in ipsis verbis to comply with the written description requirement").

Second, TEFLabs makes a convoluted argument that "[n]o 'person of ordinary skill' approach is required in this case to determine that . . . the omission of the compound from the provisional and two non-provisional applications was deliberate; that Plaintiff had canceled the

[10] At the hearing, TEFLabs cited *In re Ruschig*, 54 C.C.P.A. 1551 (1997) in support of its argument that it was unnecessary to follow the "person of ordinary skill in the art" standard. However, contrary to TEFLabs's contention, the *Ruschig* court did apply that standard to determine whether the chemical compound of the claim was sufficiently described therein. *Id.* at 1558-59 ("The issue here . . . is a question of fact: Is the compound of claim 13 described therein? Does the specification convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound?").

claim for the compound and admitted that it was not in the specification; that no written description was ever provided for the claimed compound; that the structure format was changed; that Plaintiff misrepresented [sic] structure 284G for the required written description; and that claim 1 could not have overcome the previously asserted written description rejection without misrepresentation and concealment." Reply at 4. As best as the court can decipher, TEFLabs argues as follows: Claim 26 of the '683 Application claimed the same compound that is in Claim 1 of the '165 Patent; the patent examiner rejected Claim 26 for inadequate written description; the Applicants "admitted" to the examiner that the compound was not in Claim 26 and canceled Claim 26, thereby canceling the subject matter of Claim 26; but then the Applicants reintroduced the same compound that was the subject of the rejected Claim 26 by "relying on a false structure" in the newly-added Claim 33.

Setting aside the fundamental defect in TEFLabs's argument—that no authority permits TEFLabs to ignore the "person of ordinary skill" standard—this perplexing argument is also flawed. It appears to be directed primarily toward TEFLabs's inequitable conduct defense, discussed below. To the extent that it is a written description defense, TEFLabs seems to be saying that Claim 1 of the '165 Patent does not meet the written description requirement because Claim 26 of the '683 Application did not meet the written description requirement, and the two claims are the same. However, TEFLabs does not explain how the two claims are the same, or why Claim 26 failed to meet the written description requirement in the first instance, nor does it cite to any specific evidence to shed light on these conclusions.[11] Without this information, the court cannot divine why TEFLabs believes Claim 1 fails to meet the written description requirement. Defendant's argument succumbs for that reason.[12]

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[11] TEFLabs cites only isolated "page numbers" within the *unpaginated* '683 Application file, with no further explanation or argument about why that portion of the application file supports TEFLabs's argument.

[12] Even so, AAT has provided competent expert evidence explaining how each of TEFLabs's nested conjectures is incorrect. First, AAT's expert found "no evidence [in the patent history] that the Applicants represented in any way that the compound was unsupported by the specification or that they cancelled the subject matter of claim 1 of the '165 patent." *See* Patton Surreply Decl. at ¶ 8. Instead, "Claims 22 and 24-26 were cancelled for simplicity, but the subject matter of the issued claim remained encompassed by Claims 21 and 23." *Id.* *See also* DMSJ at Ex. 12 (Amendment and Response to Accompany Request for Prioritized Examination dated August 28,

In sum, TEFLabs's written description arguments are hopelessly flawed for multiple reasons. Because TEFLabs has failed to provide clear and convincing evidence on any element of its written description defense such that a reasonable jury could invalidate the patent, TEFLabs's motion for summary judgment of invalidity on the basis of written description is **denied**. AAT's motion for summary judgment of no invalidity on the basis of written description is **granted**. *See Eli Lilly*, 251 F.3d at 962 ("[A] moving party seeking to have a patent held not invalid must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent.").

B. Enablement Requirement

A patent specification must enable a person of ordinary skill in the art to make and use the invention. 35 U.S.C. § 112 ¶ 1. "This requirement is met when at the time of filing the application one skilled in the art, having read the specification, could practice the invention without undue experimentation." *Cephalon, Inc. v. Watson Pharm., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013) (citation omitted).

TEFLabs originally challenged the validity of the '165 Patent as failing to meet the enablement requirement. DMSJ at 11. TEFLabs then appeared to have abandoned this argument, as it did not respond to AAT's counter-arguments or even mention enablement in its Reply. *See*

2013) ("[Claim 26 is] canceled . . . Claim 33 specifies a compound, support for which is found in Claim 23 and throughout the specification, see e.g. compound 284, example 14, page 83."). Second, AAT's expert found no evidence that the examiner relied on or accepted a "false" structure. *See* Patton Surreply Decl. at ¶ 9 ("TEFLabs alleges that the Applicants relied on a 'false' structure (284G) to establish adequate written description for the Fluo-8 AM compound of Claim [1] . . . . I have reviewed and compared the disclosures made in the provisional and utility patent applications and I disagree with TEFLabs' conclusion that the compound was somehow falsified . . . . [T]here is no evidence or suggestion that the cited structures in the utility application were hidden in any way. Rather the making and use of the structures were extensively described and supported, and a person of ordinary skill in the art would have understood this. As such, there can be no deception, because these structural changes were supported by the extensive synthetic details which show one of ordinary skill how to make such compounds."). Finally, AAT's evidence supports that to the extent there was a typographical error in the 284G structure depicted in the published application, that error bears no relation to TEFLabs's argument regarding the adequacy of the patent's written description. *See* Patton Decl. at ¶¶ 54-55 (clerical error in the published application was immaterial to applicants' reliance on the 284G structure; applicants relied on 284G structure to show support for the H group at the K position of claim 33, and the typographical error was unrelated to that substitution at position K; typo was also unrelated to the addition of AM esters to the compound).

Collins v. City of San Diego, 841 F.2d 337, 339 (9th Cir. 1988) ("It is well established in this Circuit that claims which are not addressed in the . . . brief are deemed abandoned.") (citation omitted). At the hearing, TEFLabs confirmed that it had dropped its enablement defense.

Nevertheless, AAT moves affirmatively for a summary judgment of no invalidity on the basis of enablement. To that end, AAT has provided competent and uncontroverted expert evidence explaining how different portions of the '165 Patent specification would assist a person to make and use the compound of Claim 1 without undue experimentation. First, Figures 6 and 7 of the specification disclose two methods of synthesis of a fluo indicator with AM esters and indicate that the substituents may be varied. Then, the specification at columns 57-60 provides synthesis details for arriving at a compound that differs from Fluo-8 AM by a single substituent (i.e., the substituent at position K). Finally, example 14 of the specification provides detailed disclosure for how to generate a similar molecule with that substituent that is the same as in Fluo-8 AM (i.e., with a hydrogen in place of a methyl group at position K). Patton Decl. at ¶¶ 31-32; '165 Patent at col. 77-80.

AAT has shown that TEFLabs failed to demonstrate by clear and convincing evidence that the '165 Patent does not meet the enablement requirement. AAT has also provided uncontradicted evidence as to why the '165 Patent does meet the enablement requirement. As such, AAT's motion for summary judgment of no invalidity on the basis of enablement is **granted**.

C. Anticipation

1. Legal Standard

If the claimed invention was "described in a printed publication" either before the date of invention, or more than one year before the U.S. patent application was filed, then that prior art anticipates the patent. 35 U.S.C. § 102(a)-(b). The anticipation inquiry proceeds on a claim-by-claim basis. *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). That is, "[t]o anticipate a claim, a single prior art reference must expressly or inherently disclose each claim limitation. But disclosure of each element is not quite enough—this court has long held that anticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim." *Id.* (citations omitted).

2. Differences Between the Invention Claimed in Tsien Patent and '165 Patent

TEFLabs alleges that the Tsien Patent (through its disclosure of Fluo-2) discloses the compound of Claim 1 of the '165 Patent (i.e., Fluo-8 AM). The patent examiner expressly considered and rejected this argument. *See* Carter Decl. at Ex. C (Notice of Allowability of '165 Patent, dated May 15, 2014) at 3. Understanding the argument requires some background on the teachings of the Tsien Patent.

The Tsien Patent claims a genus of calcium indicators. It expressly discloses the chemical structures for five calcium ion indicators: the rhodamine calcium ion indicators Rhod-1 and Rhod-2, and the fluo calcium ion indicators Fluo-1, Fluo-2, and Fluo-3.[13] Sometime after the Tsien Patent was issued, another fluo calcium ion indicator called "Fluo-4" was introduced to the market.[14] According to AAT, by 2007, "the most well-known and most oft used fluo indicators for intracellular calcium detection were Fluo-3 and Fluo-4." Patton Decl. at ¶ 26(j). As stated above, AAT sells a fluorescent calcium ion indicator called Fluo-8 AM,[15] which is an embodiment of Claim 1 of the '165 Patent.

The compounds in the genus of indicators disclosed in the Tsien Patent share a generic formula. The base structure for the disclosed fluo acid compounds is below:

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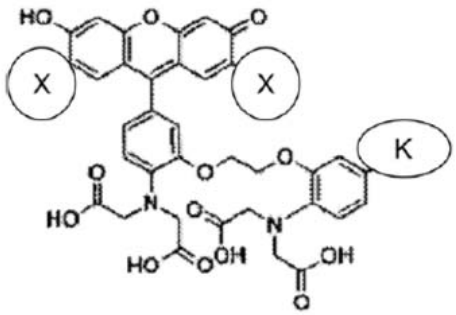
[13] The three disclosed fluo indicators do not have AM esters (and are therefore sometimes referred to as Fluo-1 acid, Fluo-2 acid, or Fluo-3 acid). *Id.* at ¶ 34.

[14] It is disputed whether Fluo-4 was claimed in the Tsien Patent or whether Fluo-4 is the embodiment of a patent owed by a different entity. *Compare* Minta Decl. [Docket No. 36-5] at ¶ 10 ("Molecular Probes made Fluo-4, a compound claimed in the Tsien Patent called Fluo-4, and paid royalties to UC Berkeley [the assignee of the Tsien Patent].") *with* Patton Decl. at ¶ 26(l) (Fluo-4 was patented in 1996) *and* Surreply at 1-2 ("In 2001-2001, TEFLabs willfully infringed Molecular Probes' U.S. Patent No. 6,162,931 (the '931 Patent) directed to Fluo-4 (the next generation fluo indicator after Tsien's disclosures of Fluo-2 and Fluo-3). *Molecular Probes v. Tex. Fluorescence Labs, Inc.*, No. 3:02-cv-461 (N.D. Cal.) . . . . [T]he case settled with TEFLabs taking a license to the '931 Patent in order to have the right to continue to sell the otherwise infringing Fluo-4 product."). For purposes of this motion, it is irrelevant who invented Fluo-4; what matters is that Fluo-4 was popular in the market before Fluo-8 was introduced, which the parties do not dispute.

[15] AAT named this compound Fluo-8 AM ostensibly because it was twice as bright as Fluo-4. Diwu Decl. at ¶ 11.



The circled Xs and K represent sites at which variable substituents[16] may be found. For example, the Fluo-2 molecule has hydrogen (H) at position X and a methyl group (CH_3) at position K, whereas the Fluo-3 molecule has chlorine (Cl) at position X and a methyl group at position K:

Molecule	**X position**	**K position**
Fluo-2	H	CH_3
Fluo-3	Cl	CH_3

By TEFLabs's own admission, there are at least two differences between the structure of the Fluo-8 AM claimed in the '165 Patent and the Fluo-2 compound disclosed in the Tsien Patent: (1) the Fluo-8 AM molecule has hydrogen at the K position; and (2) Fluo-8 AM has AM esters. *See* DMSJ at 39 ("The only two differences between [Fluo-8 AM] [and] the Fluo-2 example presented in the Tsien patent and the Minta paper are the acetoxymethyl ('AM') ester form and the 'H' versus 'CH_3' substituent at position 'k' . . . ."); Reply at 6 ("There were only 2 differences between the compound of claim 1 and the Fluo-2 example in the Tsien patent - AM esters and the affinity substituent k=H rather than CH_3"). In fact, the patent examiner's "no anticipation" finding was based on one of these admitted differences; namely, that Fluo-8 was not anticipated by Fluo-2 because the latter had a methyl group at the K position. *See* Carter Decl. at Ex. C at 2-3 (Fluo-8, as the elected compound in claim 33, "is not the . . . (AM) ester of the compound fluo-2 of Tsien.

[16] A substituent is an atom or a group of atoms substituted in the place of a hydrogen atom on a parent chain of a hydrocarbon. Patton Decl. at ¶ 23(g).

The compound in canceled claim 34 is the AM ester of fluo-2. The compounds differ by a methyl group. This compound is not anticipated.").

TEFLabs's admission alone is fatal to its motion for summary judgment, because an anticipation defense requires TEFLabs to show that the Tsien Patent "expressly or inherently disclose[s] . . . all elements of a claimed invention arranged as in the claim," *Finisar Corp.*, 523 F.3d at 1334, but TEFLabs has not identified where in the Tsien Patent the two admitted differences identified above were disclosed.

3. Disclosure of Genus

TEFLabs also contends that the Tsien Patent anticipated Fluo-8 because it claims a genus of indicators, a species of which is Fluo-8. However, "[i]t is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus." *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006). "There may be many species encompassed within a genus that are not disclosed by a mere disclosure of the genus. On the other hand, a very small genus can be a disclosure of each species within the genus." *Id.*

According to AAT's expert, Claim 1 of the Tsien Patent claims a broad genus of calcium indicators. Patton Decl. at ¶¶ 39-40. The genus shares a generic formula, but includes 11 sites,[17] each of which has up to eight substituent options; the permutations of these substituents means the Tsien Patent encompasses over 20 billion compounds with "dramatically different physical and functional properties, with no guidance as to those with superior cell loading ability and brightness." *Id.* at ¶¶ 40-41. Of these possible permutations, the Tsien Patent discloses only five specific embodiments. *Id.* at ¶ 42. Thus, AAT argues, one of ordinary skill would not be able to envision the billions of other species encompassed within this vast genus, much less the particular Fluo-8 AM species that is the compound of claim 1 of the '165 Patent. *Id.* at ¶ 45. *Accord Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1084 (Fed. Cir. 2008) (affirming district court's holding of no anticipation where "the description of the genus would not lead a person of ordinary skill to a 'small recognizable class with common properties'") (citation omitted).

[17] The sites are designated as E1, E2, W, X, Q1, Q2, Y, Z, Z1, Z3, and Z4 in the claim.

TEFLabs responds that Patton's estimate of the number of possible compounds claimed in the Tsien Patent is exaggerated. According to TEFLabs, the practice in the industry is to keep the substituents at certain sites fixed or limited to a smaller subset of options. *See* Reply at 5. Thus, rather than containing billions of possibilities, the genus claim in the Tsien Patent was in reality restricted to only "36 possible combinations of substituents." *Id.* In support of this position, TEFLabs cites to a table in the declaration of Dr. Minta ostensibly showing 18 fluo indicators that were commercially available in 2006. *See* Minta Decl. at ¶ 18, Table 3 (referring to information in DMSJ Ex. 7 (Simpson (2006) article entitled "Fluorescent Measurement of [Ca^{2+}]")).

The underpinnings of TEFLabs's argument are flawed. There is no suggestion that the 18 listed indicators were the only ones on the market, nor that the products available in 2006 were exemplary of all fluo indicators that had been on the market since the issuance of the Tsien Patent. Thus, on its face, TEFLabs's cultivated list of selected products is insufficient to show that in practice, the genus claim of the Tsien Patent encompassed only a limited number of species. Next, AAT's expert directs the court to examples of indicator products with changes at the variable positions that TEFLabs claims were "fixed" in industry practice. *See* Patton Surreply Decl. at ¶ 15 ("I disagree with TEFLabs' contention that there were only 36 possible combinations . . . at the time of the invention in 2007 or that industry practice fixed 7 . . of the 11 variable positions in the Tsien claim. In fact, TEFLabs itself marketed products as early as 1998 with changes to at least three of these variables . . . . It is my understanding that all of the variable positions of the Tsien patent have been pursued by many chemists, including Dr. Minta himself."). AAT also disputes whether TEFLab's list is accurate. AAT asserts that TEFLabs's list includes calcium indicators ("Oregon Green" and "Calcium Green") that are not fluo indicators. *See* Patton Surreply Decl. at ¶ 18 ("[T]he Oregon Green BAPTA and Calcium Green indicators are not fluo indicators, so my understanding that no one made a commercial intracellular calcium indicator with [hydrogen at the K position] until Dr. Diwu and his co-inventors did . . . still stands. Moreover, nothing about these different and distinct indicators would have prompted one of ordinary skill in the art to look at them in order to solve the problems that existed with fluo calcium ion indicators at the time of the invention in 2007.").

In sum, AAT has shown that TEFLabs failed to demonstrate by clear and convincing evidence that the '165 Patent was invalid because it was anticipated by prior art. For the above reasons, TEFLabs's motion for summary judgment on anticipation is **denied**, and AAT's motion for summary judgment of no anticipation is **granted**.

D. Obviousness

1. Legal Standard

The Patent Act forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103.

"Generally, a party seeking to invalidate a patent as obvious must demonstrate by clear and convincing evidence that a skilled artisan would have had reason to combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so." *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068-69 (Fed. Cir. 2012). "[W]hile an analysis of any teaching, suggestion, or motivation to combine known elements is useful to an obviousness analysis, the overall obviousness inquiry must be expansive and flexible." *Id.* at 1069 (*citing KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 419 (2007)).

Thus, to resolve the issue of obviousness, the court considers factual questions including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the pertinent art; and (3) differences between the claimed invention and the prior art. *KSR*, 550 U.S. at 406. The court may also consider "secondary considerations," such as "commercial success, long felt but unsolved needs, [and] failure of others," to "give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Id.* (*quoting Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). "Another indicia of non-obviousness of a product is the acclamations it receives when it is released, and the copying that occurs," although "a showing of copying is only equivocal evidence of non-obviousness in the absence of more compelling objective indicia of other secondary considerations." *Ecolochem, Inc. v. S. California Edison Co.*, 227 F.3d 1361, 1380

(Fed. Cir. 2000). The secondary evidence of nonobviousness is "often the most probative and determinative of the ultimate conclusion of obviousness or nonobviousness." *Pro-Mold and Tool Co., Inc. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

"Where a skilled artisan merely pursues 'known options' from a 'finite number of identified, predictable solutions,' the resulting invention is obvious under Section 103." *In re Cyclobenzaprine Hydrochloride*, 676 F.3d at 1070 (*quoting KSR*, 550 U.S. at 421). "Where, however, a defendant urges an obviousness finding by merely throwing metaphorical darts at a board in hopes of arriving at a successful result, but the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful, courts should reject hindsight claims of obviousness." *Id.* (quotations omitted).

2. Examiner's Determination of Non-Obviousness

"[A] party challenging [a presumptively valid patent] shoulders an enhanced burden if the invalidity argument relies on the same prior art considered during [the patent] examination." *Tokai*, 632 F.3d at 1367.

The patent examiner, in granting the '165 Patent, withdrew its previous finding of obviousness on the basis of Fluo-8's unexpected results.[18] Carter Decl. at Ex. C at 3. In doing so, the examiner looked at the same prior art (i.e., the Tsien Patent and the fluo indicators disclosed therein) on which TEFLabs's obviousness argument relies. Specifically, the examiner stated that "H to Me [hydrogen to methyl group] analogs are generally *prima facie* obvious" but found "the affidavit of inventor Diwu filed on August 28, 2013 . . . sufficient to rebut such a rejection on the grounds of unexpected results." *Id.* The examiner finding of non-obviousness focused on the fact that Fluo-8 performed better than other previously-known fluo indicators disclosed in the Tsien Patent. *See id.* ("Since the compound . . . is better than the Tsien compounds in various calcium imaging assays . . . any possible 103(a) [obviousness] rejection over Tsien for this compound has

[18] The doctrine of unexpected results is based on the principle that "that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious. The principle applies most often to the less predictable fields, such as chemistry, where minor changes in a product or process may yield substantially different results." *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) (reversing obviousness rejection where applicant presented evidence that compound with increased molecular weight produced dramatically superior results).

been overcome."). The patent examiner also noted that Fluo-2 was an unlikely lead compound. Carter Decl. at Ex. C at 3 ("[T]he fluo-2 compound was described by Tsien as the poorest performer in the patent specification . . . which gives little motivation to select this compound as one for further manipulation, i.e. demethylation.").

Of course, the fact that the examiner determined that Claim 1 was not obvious does not alone resolve the question. The court thus turns to the parties' arguments.

3. *Prima Facie* Obviousness

TEFLabs contends that "the compound of claim 1 is an obvious combination of prior art elements." DMSJ at 40. However, this argument fails to cite to any evidence regarding what a person of ordinary skill in the art would have understood at the time of patent filing. This reason alone is sufficient to deny TEFLabs's motion for summary judgment. *Advanced Media Networks LLC v. Row 44 Inc.*, No. CV 12-11018 GAF JCGX, 2014 WL 5623951, at *5 (C.D. Cal. Nov. 4, 2014) ("[B]ecause [defendants'] motion [for summary judgment] lacks the most basic information regarding what a skilled artisan would have considered obvious at the time of the invention, the argument cannot advance past that point and the Court therefore does not address the numerous other flaws in the pending motion.").

In any event, even if the court overlooks TEFLabs's foundational failure, its obviousness arguments are still inadequate. For patents that claim new chemical compounds, the question of "*prima facie* obviousness . . . generally turns on the structural similarities and differences between the claimed compound and the prior art compounds." *Otsuka Pharm. Co., Ltd. v. Sandoz Inc.*, 678 F.3d 1280, 1291 (Fed. Cir. 2012) (citation omitted). Whether a new chemical compound would have been *prima facie* obvious follows a two-part inquiry. *Id.* "First, the court determines whether a chemist of ordinary skill would have selected the asserted prior art compounds as lead compounds, or starting points, for further development efforts." *Id.* Second, the court determines "whether the prior art would have supplied one of ordinary skill in the art with a reason or motivation to modify a lead compound to make the claimed compound with a reasonable expectation of success." *Id.* at 1292 (citation omitted).

With respect to the first step of the inquiry, a lead compound is "a compound in the prior

art that would be most promising to modify in order to improve upon its . . . activity and obtain a compound with better activity." *Id.* at 1291 (citation omitted). "[A] lead compound is a natural choice for further development efforts." *Id.* "In determining whether a chemist would have selected a prior art compound as a lead, the analysis is guided by evidence of the compound's pertinent properties." *Id.* at 1292 (citation omitted).

Such properties may include positive attributes such as activity and potency; adverse effects such as toxicity, and other relevant characteristics in evidence. *See Eisai v. Dr. Reddy's Labs, Ltd.*, 533 F.3d 1353, 1358 (Fed. Cir. 2008) (considering a prior art compound's lipophilicity and low molecular weight); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1363 (Fed. Cir. 2007) (considering the "strength, solubility, and other known chemical characteristics" of a prior art saltforming acid). "Absent a reason or motivation based on such prior art evidence, mere structural similarity between a prior art compound and the claimed compound does not inform the lead compound selection." *Otuskai*, 678 F.3d at 1292 (some citations omitted).

TEFLabs simply asserts that "Fluo-2 is a 'lead compound' (along with Fluo-1 and Fluo-3) and is a logical starting point for investigating competitive alternatives to Fluo-4." Reply at 6. This is conclusory attorney argument with no evidence cited to support it.

In contrast, AAT has provided expert evidence explaining why Fluo-2 is not a lead compound. Specifically, the Tsien Patent teaches that an electron withdrawing group is necessary at the X position for a fluo calcium indicator to be useful for intracellular detection; otherwise, the fluorescence signal of the indicator would be quenched. Patton Decl. at ¶ 36. Fluo-3 has an electron-withdrawing group (Cl) at the X position, whereas Fluo-2 has a non-electron-withdrawing group (H), so the Tsien Patent taught that Fluo-3 was a more desirable compound than Fluo-2. *Id.* at ¶ 35. *See also* Tsien Patent at cols. 12:34-37 ("In most applications, fluo-3 will be generally preferable over fluo-1 and fluo-2 because of its lesser sensitivity to pH and its larger fluorescence enhancement on binding [calcium ion]"); 21:55-56 ("[F]luorescence of fluo-2 was almost completely quenched as the pH was titrated from pH 7.7 to 4.1 in the absence of [calcium ion]"); and 21:65-22:1 ("[B]ecause protonation has such a powerful effect on the fluorescence and is spectrally indistinguishable from a drop in [calcium ion], fluo-2 is too pH sensitive for general

use."). According to AAT, in developing their inventions, Dr. Diwu and his colleagues discovered that it was not necessary to have an electron withdrawing group to make a useful calcium indicator. Diwu Decl. ¶ 14.

Against this evidence, TEFLabs responds with declarations from Dr. Minta and Dr. Joseph Kao, an expert with a doctorate in physical chemistry who was on Dr. Tsien's research team at UC Berkeley. *See* Reply at 6-7; Minta Decl. at ¶ 42; Kao Decl. [Docket No. 36-3] at ¶ 7. Dr. Minta contends that the hydrogen at position X in Fluo-2 is actually "mildly electron withdrawing"; Dr. Patton responds that "[t]his is scientifically incorrect" and that hydrogen is non-electron-withdrawing. Patton Surreply Decl. at ¶ 22. Dr. Kao takes issue with the examiner's reference to Tsien's statements that Fluo-2 was the "poorest performer." Dr. Kao notes that "Roger Tsien is extremely modest and cautious about the utility of his molecules" and simply because he counseled against using Fluo-2 for *general use* did not mean he discounted the utility of Fluo-2 entirely. Kao Decl. at ¶ 8.

These quibbles miss the forest for the trees. While TEFLabs is busy attacking AAT's evidence showing that Fluo-2 was *not* a lead compound, it provides no affirmative evidence that Fluo-2 *was* a lead compound. This means that TEFLabs has failed to meet its burden on summary judgment, and that AAT has met its burden.

4. Objective Indicia of Nonobviousness

Finally, AAT points the court to evidence regarding objective indicia of non-obviousness. First, the fact that TEFLabs copied AAT's invention supports a finding of non-obviousness. *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 991 (Fed. Cir. 1988). TEFLabs admitted that a prospective customer asked whether it manufactured Fluo-8 AM in early 2010, and thereafter TEFLabs "purchased Fluo-8 from AAT" and analyzed it. TEFLabs began selling Fluo-8 AM in the second Q2 2010. Second, failures by others to create an improved calcium indicator and the resulting unmet need are also strong objective indicia of non-obviousness. Diwu Decl. at ¶¶ 7-8 (efforts at Molecular Probes, Molecular Devices, and AnaSpec from 1993-2006 to address the weakness of the known fluo indicators such as Fluo-3 and Fluo-4 were unsuccessful "in part because [we] followed the Tsien reference's teaching that focused on compounds with electron-

withdrawing groups at . . . the X position"). Third, the immediate commercial success of Fluo-8 AM is another strong indicator of nonobviousness. *See* Diwu Decl. at ¶ 17 (AAT's total Fluo-8 AM revenue increased more than 100% year over year from 2007 to 2009, effectively creating a new market segment); ¶ 18 (in 2008 and 2009, before the patent issued, three of market leaders in the high throughput screening space sought out AAT and licensed the patent application which eventually issued as the '165 Patent under no threat of litigation); at ¶ 17 (by 2010, AAT's yearly Fluo-8 AM sales totaled more than a half million dollars); ¶ 19 (three leading high throughput screening companies have purchased Fluo-8 AM to specifically replace Fluo-3 AM or Fluo-4 AM); ¶ 17 (AAT achieved these sales without any salesperson in the field). Finally, TEFLabs's sale of its admittedly infringing copy of Fluo-8 AM, and its own sales materials extolling the superiority of Fluo-8 over its predecessors, are indicia of non-obviousness. *See generally* Carter Decl. at Exs. I, J, K, L, M, N.

TEFLabs responds to this with weak evidence of its own. First, as proof that Fluo-8 was not successful, TEFLabs cites to a declaration from Dr. Minta that Fluo-8 "represents less than 10% of the fluo indicator market." Minta Decl. at ¶ 15. But this conclusion rests on the thinnest of reeds, for Dr. Minta based it on his review of "UC Berkeley receipts that I can locate" for sales of Fluo-3 and Fluo-4 between 2003 and 2007, and general revenue reports comparing AAT and TEFLabs's revenues between 2007 and 2014. This does little to shed light on Fluo-8's market share and how it has changed over time. Second, TEFLabs argues that it simply opted not to commercialized Fluo-8, even though the Tsien Patent ostensibly covered it, because it opted to pursue other business strategies. This is belied by TEFLabs's marketing materials, which explain that Fluo-8 was commercialized *after* Fluo-3 and Fluo-4 because TEFLabs did not appreciate its brightness until then. Carter Decl. at Ex. L at 19.

In sum, TEFLabs has failed at the outset to make a case of obviousness by not providing evidence regarding what a person of ordinary skill in the art would have considered to be obvious at the time of the invention. In addition, TEFLabs has failed to submit evidence demonstrating why Fluo-2 would have been selected as a lead compound. In contrast, AAT has presented evidence of the objective indicia of non-obviousness, as well as evidence that Fluo-8 AM

produced unexpectedly superior results when compared with the other fluo indicators available in the market at that time. For these reasons, TEFLabs's motion for summary judgment of invalidity on the basis of obviousness is **denied**, and AAT's motion for summary judgment of no invalidity on the basis of obviousness is **granted**.

E. Inequitable Conduct

1. Legal Standard

Where a patent applicant breaches the duty to prosecute a patent application with candor and good faith, it may result in a finding of inequitable conduct. 37 C.F.R. § 1.56(a) (2004); *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1128 (Fed. Cir. 2006). Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). "[T]he remedy for inequitable conduct is the 'atomic bomb' of patent law." *Id.* at 1288. "Unlike validity defenses, which are claim specific . . . inequitable conduct regarding any single claim renders the entire patent unenforceable." *Id.* "[B]ecause the penalty for inequitable conduct is so severe . . . [t]he need to strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context is paramount." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008).

To prove inequitable conduct, the accused infringer must present "evidence that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [PTO]." *Star Scientific*, 537 F.3d at 1365 ("The burden of proving inequitable conduct lies with the accused infringer."). Intent and materiality are separate requirements. "A district court should not use a 'sliding scale,' where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa. Moreover, a district court may not infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality." *Therasense*, 649 F.3d at 1290. "[A] threshold level of each element—i.e., both materiality and intent to deceive—must be proven by clear and convincing evidence. And even if this elevated evidentiary burden is met as to both elements, the district court must still

balance the equities to determine whether the applicant's conduct before the PTO was egregious enough to warrant holding the entire patent unenforceable." *Star Scientific*, 537 F.3d at 1365 (citations omitted). Thus, "even if a threshold level of both materiality and intent to deceive are proven by clear and convincing evidence, the court may still decline to render the patent unenforceable." *Id.*

The intent element requires the accused infringer to "prove that the patentee acted with the specific intent to deceive the PTO. A finding that the misrepresentation or omission amounts to gross negligence or negligence under a 'should have known' standard does not satisfy this intent requirement." *Therasense*, 649 F.3d at 1290 (citation omitted). "Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence." *Id.* "However, to meet the clear and convincing evidence standard, the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence." *Id.* (citations omitted). "Indeed, the evidence must be sufficient to require a finding of deceitful intent in the light of all the circumstances." *Id.* (emphasis in original, quotation omitted). When there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found. *Id.* at 1290-91. In a case involving nondisclosure of information, "the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." *Id.* at 1290.

"The materiality required to establish inequitable conduct is but-for materiality." *Therasense*, 649 F.3d at 1291. "When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art." *Id.* "Hence, in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference." *Id.* "In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction." *Id.* at 1291-92.

"Determining at summary judgment that a patent is unenforceable for inequitable conduct is permissible, but uncommon." *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309,

1313 (Fed. Cir. 2006). When a party has failed to established inequitable conduct by clear and convincing evidence, summary judgment is properly granted against that party. *See Astrazeneca Pharms. LP v. Teva Pharms. USA, Inc.*, 583 F.3d 766, 777 (Fed. Cir. 2009) (affirming summary judgment of no inequitable conduct, when the factual premises could not be established by clear and convincing evidence).

2. TEFLabs's Basic Evidentiary Failures

TEFLabs makes conclusory, scattershot allegations of instances of inequitable conduct supported by a handful of impenetrable evidentiary citations.[19] These unsupported attorney arguments are insufficient to meet TEFLabs's burden. *See Digital Control*, 437 F.3d at 1313 ("A genuine issue of material fact [regarding inequitable conduct] is not raised by the submission of merely conclusory statements or completely insupportable, specious, or conflicting explanations or excuses.") (citations omitted).

Notwithstanding this evidentiary failure, TEFLabs's arguments are still insufficient to the extent they accuse "AAT Bioquest" or "Plaintiff" of engaging in inequitable conduct, because they fail to demonstrate the specifics of the inequitable conduct. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009) ("[T]o plead the 'circumstances' of inequitable conduct with the requisite 'particularity' under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.").

3. TEFLabs's Arguments Regarding Inequitable Conduct

a. Opportunities for Design Around Tsien Patent

[19] Those are mass citations to the approximately 1,000 pages in the patent files of the '452 Application, the '753 Application, the '683 Application, and two other patent applications that TEFLabs contends are related to the '165 Patent. *See, e.g.*, DMSJ at 45 ("In Base Application '753, AATBioquest falsified three compounds (284, 304, and 306) from the compounds identified in the provisional application; and submitted new compounds 365 and 366 while still claiming the benefit of the provisional application filing date. The falsified and new compounds are fundamental to the claims in subsequent applications. [12040753_FILE_HISTORY]."). *See also supra* n. 9. The only evidentiary citation for TEFLabs's inequitable conduct arguments in its Reply brief is to the declaration of Dr. Minta at paragraph 52. Reply at 8. For reasons explained below, this *de minimis* evidence fails to meet TEFLabs's elevated evidentiary burden to demonstrate inequitable conduct by clear and convincing evidence.

TEFLabs contends that its table of 18 fluo indicators offered for sale in 2006 establishes that "there was ample opportunity for a design-around of the Tsien claims." *See* Reply at 8; Minta Decl. at ¶¶ 18, 52. The court explained earlier why this table has weak evidentiary value. *See supra* Section III.C.3. Furthermore, this argument plainly fails to meet the required materiality and intentionality elements of the inequitable conduct standards. There is no support for TEFLabs's contention that the existence of other fluo indicator compounds that were not covered by the Tsien Patent demonstrates that AAT's creation of Fluo-8 was a material, affirmative misrepresentation intended to deceive the PTO.

b. Representations Made to Patent Examiner

TEFLabs alleges that AAT made material misrepresentations and omissions in order to overcome the patent examiner's initial rejections of the '683 Application. These allegations of inequitable conduct simply rehash TEFLabs's invalidity arguments: (1) "the reintroduction of claim 33 . . . with a new structural format, new independent claim, and false compound 284G for support"; (2) "the misleading argument that Tsien claimed vast number of compounds, when most substituents had been fixed in 18 commercially-available Fluo compounds"; (3) "the false argument that there was little guidance for selecting the compound of claim 1"; (4) "the omission in the specification, and in all prosecution history, of the established and preferred role of position "k" to modify affinity"; (5) "the failure to disclose the Orgeon Green and Calcium Green use of k=H"; (6) "the failure to correct the examiner's misconceptions in the Reasons for Allowance (Fluo-8 AM does not require "further processing" or "demethylation" of Fluo-2)." Reply at 9. TEFLabs cites no evidence to support of these allegations, and does not even provide attorney argument about why these supposed misrepresentations are material or made with the intent to deceive the patent examiner.

c. Sham specifications

TEFLabs also contends the '165 Patent specification creates unused "dummy" positions[20] that conceal the identity of Fluo-8 AM. *See* Reply at 9 (arguing that AAT "submitt[ed] a sham specification which presented a large number of useless (and likely untested) example compounds

[20] Those positions are R3, R4, j, m, n, V, T, and U.

to present the appearance of a legitimate research effort" and "claim[ed] a large number dummy substituents at positions j, m, n, V, R3, and R4 without presenting any example of substituents at those positions in any of the four utility patent applications"). Again, TEFLabs cites no evidence in support of this argument. AAT's evidence supports that these positions are not "dummy" positions, and AAT has "commercialized and is pursuing patent protection on additional compounds with different molecules at these alleged 'dummy' positions." Diwu Decl. at ¶ 20.

d. Deceptive naming and failure to disclose Fluo-2

TEFLabs contends that AAT committed inequitable conduct by "not disclosing elected species compound was a Fluo-2 compound until the examiner cited Fluo-2" and "renaming Fluo-2 AM as Fluo-8H, but not disclosing Fluo-8H (and its affinity relationship with Fluo-8 in the affidavits)." Reply at 9-10. The patent file shows otherwise. See Carter Decl. at Ex. Q (Diwu affidavit to patent examiner in '683 Application dated March 2, 2011, including structural comparison of Fluo-8 AM with Fluo-2 compounds).

e. Falsifying compounds

TEFLabs argues that AAT "falsif[ied] compounds 304, 306, and 284 by removing halogens in order to backdate the priority of Fluo-2 versions to the provisional application." Reply at 10. *See also* DMSJ at 23-24 (example compounds 304 and 306 from the provisional application were "changed . . . from fluorinated compounds to the preferred Fluo-2 compounds in an application filed years later"). There is no evidence to support this argument. There is hardly *argument* to support this argument, as the court cannot determine from TEFLabs's briefing how it believes compounds 304, 306, and 284 had been changed, how those changes qualify as "falsifications," when those falsifications were presented to the patent examiner, or how those falsifications are material or significant. Moreover there is no evidence showing that these alleged falsifications were made with the requisite intent to deceive.

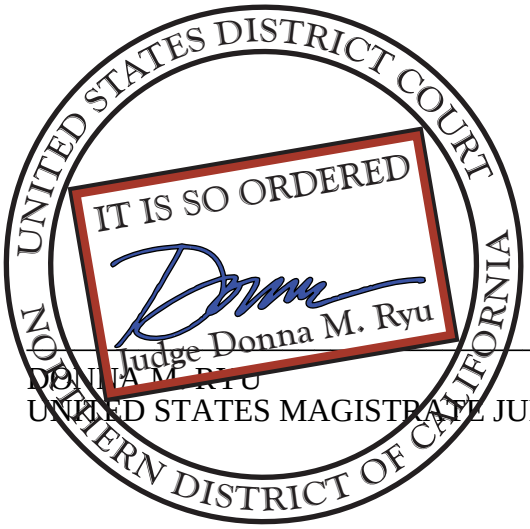
In sum, TEFLabs has failed to present clear and convincing evidence supporting a finding of inequitable conduct. TEFLabs's motion for summary judgment of inequitable conduct is **denied**, and AAT's motion for summary judgment of no inequitable conduct is **granted**.

IV. CONCLUSION

For the reasons stated above, AAT's motion for summary judgment is **granted** and TEFLabs's motion for summary judgment is **denied**. In light of this order, all pretrial and trial dates are vacated. The parties shall appear for a further case management conference on May 6, 2015, and shall file a joint updated case management conference statement by April 29, 2015.

IT IS SO ORDERED.

Dated: April 13, 2015



DONNA M. RYU
UNITED STATES MAGISTRATE JUDGE

United States District Court
Northern District of California